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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,216	12/02/2003	Timothy C. Nichols	421/29/2/2	4262

25297 7590 01/24/2007  
JENKINS, WILSON, TAYLOR & HUNT, P. A.  
3100 TOWER BLVD  
SUITE 1200  
DURHAM, NC 27707

EXAMINER
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ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1647

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/726,216

Applicant(s)

NICHOLS ET AL.

Examiner

Marianne P. Allen

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1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 13-44 and 55-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 45-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I, claims 1-12 and 45-54, in the reply filed on 11/13/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-44 and 55-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/06.

### ***Information Disclosure Statement***

The references lined through on the attached PTO Forms 1449 have been considered but will not be printed because they are not publications.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 45-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

The claims as written require only a test sample comprising a platelet VDCC polypeptide. The test sample is not required to have the platelet VDCC polypeptide present in a cell membrane. The claims have no requirement that any of the cellular constituents required for phosphatidylserine exposure on the surface of the cell be present. In the absence of these constituents, step (c) will measure nothing. Note that claim 7 requires “a surface of the test sample.” Claim 1 has no limitation that the test sample possess a surface of any kind. While claim 5 indicates that the VDCC is within a cell, it is not required to be on the cell surface. See also claim 49. The methods as written are incomplete and as such, not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 45-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 45 are confusing because the test sample is not required to have a cell where phosphatidylserine could be exposed.

Claims 3 and 47 are confusing because the limitations set forth therein do not further modify the methods of claims 1 and 45. That is, the step of isolating a gene encoding the candidate polypeptide does not further limit the method of screening candidate substances for their ability to modulate phosphatidylserine on the surface of a cell. Furthermore, not all of the candidate substances embraced by claims 2 and 46 would have a gene associated with them.

Claims 6 and 50 are confusing because the limitations set forth therein do not further modify the methods of claims 5 and 49. A recombinant cell line suitable for use appears to be implicit in the recitation of a cell in cell culture found in claims 5 and 49.

Claim 7 is confusing as it lacks antecedent basis in claim 1 for “a surface of the test sample.”

Claims 11 and 12 are confusing because they appear to require foreknowledge of what the results of the method of claim 1 will be. The claims do not make clear which candidate substances will provide an increase or decrease in phosphatidylserine exposure on the surface of the cell.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-7, 11-12, 45-46, and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunzelmann-Marche et al. in view of Malouf et al. (US 2002/0165353 A1).

Kunzelmann-Marche et al. discloses screening candidate substances for their ability to modulate phosphatidylserine exposure on the surface of a cell line that expresses receptors such as those found in platelets using flow cytometry. The reference discloses that  $Ca^{2+}$  channels in platelets would have been known to have been involved in phosphatidylserine exposure on the cell surface. See at least abstract, figures, and page 5134. The reference does not disclose the platelet voltage dependent calcium channel (VDCC) of SEQ ID NO: 2 that is encoded by the nucleic acid sequence of SEQ ID NO: 1.

Malouf et al. discloses the platelet voltage dependent calcium channel (VDCC) of SEQ ID NO: 2 that is encoded by the nucleic acid sequence of SEQ ID NO: 1.

It would have been obvious to screen candidate substances for their ability to modulate phosphatidylserine exposure on the surface of a cell line where the VDCC taught by Malouf et al. was present. One would have been motivated to do so as Malouf et al. discloses that this VDCC is found in platelets and Kunzelmann-Marche et al. teaches that calcium mobilization involving platelet calcium channels is involved in phosphatidylserine exposure on the surface of the cell. .

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Marianne P. Allen*

Marianne P. Allen  
Primary Examiner  
Art Unit 1647

*1/18/07*

mpa